REMARKS

Claims 131-150, 153, 155-162, 243 and 244 are pending. Claims 132, 134-149, 156, 157 and 159 stand withdrawn from consideration. By this Amendment, claims 131, 243 and 244 are amended without adding new matter. Favorable consideration is respectfully requested in view of the above amendments and the following remarks.

Rejections Under 35 U.S.C. § 103

Claims 131, 133, 150, 153, 155, 243 and 244 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,238,334 to Easterbrook et al. ("Easterbrook") in view of U.S. Patent No. 6,626,821 to Kung et al. ("Kung").

Claim 131, as amended, recites a process for assisting the function of a heart having an outer wall using a deformable direct mechanical ventricular assistance apparatus, with said heart disposed within a patient. The claimed process comprises, *inter alia*, exporting said at least one command instruction from said controller to assist said heart by effecting changes in volume of a drive fluid within a single continuous cavity of variable volume of said deformable direct mechanical ventricular assistance apparatus, said cavity extending circumferentially completely and continuously around said outer wall of said heart (emphasis added). Support for the recitation of a deformable direct mechanical ventricular assistance (DMVA) apparatus in claim 131 can be found, for example, at page 101, line 30, to page 102, line 16, of the specification.

Embodiments of the DMVA apparatus include a housing (or shell) and a liner. For example, the embodiment of the DMVA device shown in FIG. 2E comprises a

single continuous cavity between the liner 114 and the inner surface of the housing wall 112. The cavity extends circumferentially completely and continuously around the outer wall of the heart 30. In other words, the cavity extends infinitely around the outer wall of the heart.

The Office asserts that Easterbrook discloses a process for assisting the function of a heart, comprising "a single continuous cavity of variable volume extending circumferentially completely around the outer wall of said heart (14)." The Office references Figures 1 and 27 of Easterbrook. Figure 1 of Easterbrook shows a ventricular cuff 10 with a wrap structure including closed first and second ends 62, 63, which overlap each other when placed on a heart. Accordingly, in this cuff structure, there is no single continuous cavity that extends circumferentially completely and continuously around the outer wall of a heart.

Figure 27 of Easterbrook shows a ventricular cuff 200 including an interior chamber 202, an annular inflatable bladder 204 and a suction membrane 206. As described at column 14, lines 11-49 of Easterbrook, the cuff 200 includes an apical reinforcing support assembly including a spatula 228, a backplate reinforcement 230, and supporting rods 232. The spatula 228 is preferably made of a semi-rigid polymer (column 14, lines 22-25). The rods 232 are made of a non-flexible metal (column 14, lines 32-34). The rods provide support for the bladder as the bladder and suction membrane 206 are extended over the heart.

The DMVA apparatus recited in claim 131 is "deformable." To achieve this deformability, the housing of the DMVA apparatus is constructed of a flexible material to provide a "dynamic housing." The liner is also constructed of a deformable material. The housing is compliant and able to change shape in

response to the actuating forces applied to the heart and changes in the heart's size and/or shape. These properties of the housing allow the DMVA apparatus to be deformed to fit through small incisions (specification at page 102, lines 1-4). The flexible housing has appropriate compliance and elastic properties that allow it to absorb the systolic and diastolic actuating forces in a manner that somewhat buffers the effect of the liner on the heart. The housing can conform to the dynamic changes in the right and left ventricles throughout compression and relaxation cycles and ongoing changes in the heart size.

Applicants submit that Easterbrook does not disclose or suggest that the ventricular cuff 200 shown in Figure 27 is deformable like the DMVA apparatus recited in claim 131. In stark contrast, Easterbrook discloses that the cuff 200 includes semi-rigid and non-flexible supporting elements.

Kung does not cure the deficiencies of Easterbrook with respect to the process recited in claim 131. Kung discloses a flow-balanced cardiac wrap for enclosing a tricular region of the heart. The embodiment of the cardiac wrap 110 shown, for example, in Figure 1 of Kung, includes numerous inflation elements 112 arranged in parallel longitudinally. Each individual inflation element 112 defines a separate cavity of variable volume, which is inflatable to apply pressure to the heart 100 on which the wrap 112 is fitted. Kung depicts other embodiments of the wrap in Figures 7-13, 19 and 23-25, for example. Each of these other disclosed embodiments also includes multiple inflation elements, each defining a separate cavity, such that each wrap includes multiple cavities. Kung does not disclose or suggest a wrap including a single continuous cavity of variable volume extending

circumferentially completely and continuously around the wall of a heart, as recited in claim 131.

Accordingly, the Office has not articulated a reason to combine the teachings of Easterbrook and Kung to result in the process recited in claim 131. Claims 133, 150, 153 and 155, which depend from claim 131, are also patentable over the combination of Easterbrook and Kung for at least the same reasons as those for which claim 131 is patentable.

Claim 243, as amended, recites a process for assisting the function of a heart including a left ventricle, a right ventricle and an outer wall using a deformable direct mechanical ventricular assistance apparatus, the heart disposed within a patient. The recited process comprises, *inter alia*, exporting the at least one command instruction from the controller to assist the heart by effecting changes in volume of a drive fluid within a first cavity of variable volume corresponding to the left ventricle and a separate second cavity of variable volume corresponding to the right ventricle of said deformable direct mechanical ventricular assistance apparatus, the first and second cavities together extending circumferentially completely and continuously around the outer wall (emphasis added).

The Office has not identified the features of "a first cavity of variable volume corresponding to the left ventricle and a separate second cavity of variable volume corresponding to the right ventricle of said deformable direct mechanical ventricular assistance apparatus, the first and second cavities together extending circumferentially completely and continuously around the outer wall" (emphasis added) in either of Easterbrook or Kung. Accordingly, the combination of Easterbrook and Kung does not support the rejection of claim 243.

Dependent claim 244 is also patentable for at least the same reasons as those for which claim 243 is patentable. Therefore, withdrawal of this rejection is respectfully requested.

Claims 131, 133, 150, 153, 155, 243 and 255 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,971,910 to Tsitlik et al. ("Tsitlik") in view of Kung. This rejection is respectfully traversed.

As discussed above, claim 131 recites a process for assisting the function of a heart having an outer wall using a <u>deformable</u> direct mechanical ventricular assistance apparatus, with said heart disposed within a patient, which process comprises, *inter alia*, "exporting said at least one command instruction from said controller <u>to assist said heart by effecting changes in volume of a drive fluid within a single continuous cavity of variable volume</u> of said <u>deformable</u> direct mechanical ventricular assistance apparatus, <u>said cavity extending circumferentially completely and continuously around said outer wall of said heart</u>" (emphasis added).

The Office asserts that Tsitlik discloses a process for assisting the function of a heart, comprising "a single continuous cavity of variable volume extending circumferentially completely around the outer wall of said heart (36)." The Office references the apparatus 10 shown in Figure 1 of Tsitlik. The apparatus 10 includes a housing 12 having a generally cylindrical wall 14 with a membrane 22. Figure 2 shows a heart located within the housing 12.

Applicants submit that Tsitlik does not suggest that the apparatus 10 is a <u>deformable</u> DMVA apparatus, i.e., the apparatus 10, as a whole, is deformable. To

the contrary, Tsitlik includes explicit disclosure that at least strongly suggests that the apparatus 10 is not deformable.

For example, Tsitlik discloses that the apparatus includes an axial end plate 16. Also, the vertical position of conduit 44 is fixed relative to the end plate 16 (column 5, lines 55-62). As shown in Figure 1, the end plate 16 is flat and has a greater thickness than the wall 14. Applicants submit that this disclosure suggests that the end plate 16 is non-deformable.

Tsitlik also discloses that the apparatus 10 includes a deformable heart support net 52. The provision of this deformable net in the apparatus 10 also suggests that the housing 12 is non-deformable.

Tsitlik also discloses that "the device's outer dimensions are sized to fit within the chest cavity of the patient" (column 8, lines 45-46; column 14, lines 27-28). Tsitlik provides further disclosure that suggests that the housing has fixed dimensions (e.g., column 11, lines 55-62; column 13, lines 9-15). Applicants submit that this disclosure further suggests that Tsitlik's apparatus is not deformable as a whole.

Applicants further submit that each of Tsitlik's figures depicts a rigid structure having a shape that would be physiologically impossible to implant. In contrast, as discussed above, the deformable DMVA recited in claim 131 can be implanted.

In addition, Tsitlik's apparatus differs functionally from the recited DMVA apparatus. Tsitlik discloses that the barrier does not create transmural pressure (TP). This pressure results from the elasticity of the liner in a cup device. Work due to stretching the liner requires slightly more drive fluid pressure to effect the compression of the heart during systole. This same pressure difference is recovered

during diastole. Tsitlik teaches active systole only, not diastole. As such, Applicants submit that the Tsitlik apparatus does not recover the TP elastically. In contrast, the process recited in claim 131 can provide both active systole and diastole.

Applicants further submit that Kung does not cure the deficiencies of Tsitlk in regard to the process recited in claim 131. Accordingly, claim 131 is patentable.

Dependent claims 133, 150, 153 and 155 are also patentable over Tsitlik for at least the same reasons as those for which claim 131 is patentable.

For reasons discussed above, the combination of Tsitlik and Kung also does not suggest the process recited in claim 243. Accordingly, claim 243 is also patentable.

Therefore, withdrawal of this rejection is respectfully requested.

Conclusion

For the foregoing reasons, allowance of the application is respectfully requested. Should the Examiner have any questions concerning this response, to expedite prosecution, the Examiner is respectfully requested to contact the undersigned at the number given below.

Respectfully submitted,

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